

**Financial Disclosure  
Statement**

## FINANCIAL DISCLOSURE

### Clinical Investigators

This petition includes data gathered from IDE studies approved by the FDA. The companies providing the data certify that they have complied with the requirements of 21 CFR Part 54 – Financial Disclosure by Clinical Investigators. Information pertaining to these financial disclosures is on file with each sponsor, and available for review by the agency.

### Paid Consultants

In addition to disclosure of the financial arrangements between the clinical investigators and the sponsors of the IDE clinical investigations, OSMA has paid for the services of three consultants, Max Sherman, Harry McKellop, Ph.D. and Pat Campbell, Ph.D. to assist with the preparation of this reclassification petition.